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Reply to Non-Final Office Action dated May 21, 2008

**REMARKS** 

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 4 - 7 were previously cancelled, without prejudice or disclaimer of the subject matter

contained therein.

Claim 9 was found by the Examiner as being drawn to an unelected invention as defined by

a previous restriction requirement, and was previously withdrawn.

Claims 1 and 8 are herein amended. No new matter is added.

Claims 1 - 3, 8, and 9 are pending and stand rejected.

II. Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for

the claimed subject matter. Applicants respectfully traverse the Examiner's assertion that the

specification does not teach which of the variables and equations disclosed on pages 12-30 of the

specification corresponds in Claim 8 to the claimed second measurement value, the second

theoretical value, the difference between the second measurement value and the second theoretical

value, the adjusted blood flow rate, and the second predetermined acceptable ration difference.

Support for all of the above can be found in the specification as filed at page 33, lines 1-16, and at

page 34, line 19 to page 35, line 4.

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III. Claim Objections

Claims 1-3 and 8 are amended and now avoid the Examiner's objections to informalities.

IV. Rejections under 35 U.S.C. § 112

Claims 1-3 and 8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply

with the written description requirement. Specifically, the Examiner asserts that the claims contain

subject matter which was not described in the specification is such a way as to reasonably convey to

one skilled in the relevant art that the inventors, at the time the application was filed, had possession

of the claimed invention. In claim 1, the theoretical ratio value relationship Quf/Qb was

inadvertently reversed. Claim 1 is amended to overcome the rejection and Applicants thank the

Examiner for bringing this to Applicants' attention.

V. Rejections under 35 U.S.C. § 103

The rejection of Claims 1 - 3 and 8 under 35 U.S.C. §103(a) as being unpatentable over

Brugger et al. (U.S. Patent No. 6,554,789, "Brugger") is traversed. Both Brugger and Applicants

disclose an apparatus which is directed toward solving the same problem, that of providing a blood

purification apparatus for removing waste water from blood. It is to be noted, however, that while

they are directed to solving the same problem, they each operate in completely different ways. In

Applicant's invention, a first measuring means disposed in the arterial blood circuit of the blood

circuit measures the blood concentration Hta of the arterial blood circuit; a second measuring means

disposed in the venous blood circuit of the blood circuit measures the blood concentration Htv of

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the venous blood circuit; and there is additionally a calculating unit which calculates the ratio

Hta/Htv of the blood concentrations measured by the first and second measuring means. The

calculating unit then calculates the blood concentration ratio as a theoretical value obtained from a

designated formula using two parameters, a preset blood flow rate of the blood pump and a blood

purifying rate by the blood purifier. It is to be noted that the calculating unit initially calculates two

ratios. An evaluation unit then compares the blood concentration ratio as a measurement value with

the blood concentration ratio as a theoretical value to determine if they are substantially equal. If

the hematocrit value measured by the first measuring means is Hta, and the hematocrit value

measured by the second measuring means is Htv, the calculating unit calculates a measured ratio

Hta / Htv, and if the preset blood flow rate of the pump is Ob and the water removal rate of the

ultrafiltration pump is Quf, then the theoretical ratio Hta / Htv is obtained from the following

relationship:

Hta / Htv = 1 - (Quf (preset value) / Qb (preset value)).

The calculating unit calculates the measured and theoretical value ratios using the above

relationship. The evaluation unit evaluates whether the two ratios, the measured hematocrit value

ratio and the theoretical hematocrit value ratio, are substantially equal by determining whether each

of the two ratios is substantially equal to 1; or, whether the difference between the two ratios is

close to 0.

Nowhere does Brugger disclose or suggest a calculating unit which first obtains two ratios, a

measured ratio value and a theoretical ratio value, and then compares the measured ratio value to

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the theoretical ratio value to obtain an evaluation value which is used to evaluate the operation of

the blood purification apparatus.

Brugger states (see col. 21, lines 24-53) that the blood flow rate, BFR, can be prescribed by

an attending physician and input by the operator at the beginning of a treatment session. Thus, in

Brugger, the BFR is a fixed value which can be obtained from a reference chart. Brugger also states

that an optimal BFR can be obtained from the relationship BFR= (RFR+UFR)/FF, where FF is the

desired percentage of fluid to be removed from the blood stream through the hemofilter. Nowhere

does Brugger disclose or suggest doing what Applicants disclose and claim, that of obtaining two

separate ratios which are used by an evaluating unit. For example, Brugger states in col. 22, lines

52-59 that the RFR, the replacement fluid rate, is a fixed number which is prescribed by the

attending physician or can be obtained from the relationship RFR=(BFR\*FF)-UFR. It is to be noted

that neither of the resulting figures is a ratio.

Brugger does disclose (see col. 24, lines 26 - 34), a device that derives a single blood fluid

reduction ratio based upon the difference detected by sensors between the pre-treatment and post-

treatment hematocrits, and compares this single ratio with the filtration fraction value (which is not

a ratio) to issue a command to the flow restrictor to bring the difference between the readings of the

two hematocrits to zero.

Applicants' amended claim 1 recites, in combination, the structure of:

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...a calculating unit to first calculate a measured ratio value and a

theoretical ratio value and then compare said measured ratio value to

said theoretical ratio value to then calculate an evaluation value used

to evaluate operation of the blood purification device; wherein

the first measured hematocrit value Hta is divided by the

second hematocrit value Htv to obtain the measured ratio value

Hta/Htv; and a preset water removal rate Quf is divided by a preset

blood flow rate Qb to obtain the theoretical ratio value Quf/Qb;

an evaluation unit coupled to evaluate whether the evaluation

value is larger than a first predetermined acceptable ratio difference...

(underscoring added for emphasis).

The Examiner does state that Brugger does not expressly teach what is positively recited in

claim 1, that of a measured ratio value Hta/Htv; the theoretical ratio value being Qb/Quf; comparing

the measured and theoretical ratio values to obtain an evaluation value; the evaluation unit

evaluating whether the evaluation value is larger than a first predetermined acceptable ratio

difference; or the reporting unit reporting a trouble condition when the devaluation value is larger

than a predetermined value.

The Examiner then states that Brugger, however, teaches all the structural limitations of the

claims, including a pair of measuring units measuring pre-treatment hematocrit and post-treatment

hematocrit in the arterial and venous blood circuits, as well as detecting leaks and other trouble

conditions. Applicants respectfully disagree. Brugger neither discloses nor suggests the structure

of the calculating unit which calculates two separate ratio values and then calculates an evaluation

value from these two ratios, wherein the first measured hematocrit value Hta is divided by the

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second hematocrit value Htv to obtain the measured ratio value Hta/Htv; and a preset water removal

rate Quf is divided by a preset blood flow rate Qb to obtain the theoretical ratio value Quf/Qb, as is

positively recited in instant Claim 1.

As noted above, Claim 1 positively recites structure which is neither disclosed nor suggested

by Brugger and, therefore, is believed to be in condition for allowance. Claims 2, 3 and 8 depend

from amended Claim 1 and thus also avoid the Brugger reference.

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**CONCLUSION** 

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In view of the foregoing amendments and remarks, each of the presently pending claims in

this application is believed to be in immediate condition for allowance. Accordingly, the Examiner

is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number

indicated below if the Examiner believes any issue can be resolved through either a Supplemental

Response or an Examiner's Amendment.

Dated: July 28, 2008

Respectfully submitted,

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